

REMARKS

Applicants thank the Examiner for the telephonic interview of November 4, 2004 at which at least several issues presented in the Office Action dated June 10, 2004 were discussed.

Claims 1-41 constitute the pending claims in the present application. Claims 1, 13-18, 22-26, 30, 31, 34-36, and 41 have been amended. Claims 19-21, and 27-29 have been canceled. Support for the amendments may be found, for example throughout instant specification, including the claims as originally filed. No new matter has been added.

Amendment of the originally filed claims, or cancellation of any claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Claim Rejections under 35 U.S.C. §112

Claims 1, 5-31, and 34-41 are rejected under 35 U.S.C. 112, first paragraph. Applicants respectfully traverse these rejection.

The Office Action states that the specification, while being enabled for biocompatible oils recited in claim 3, does not reasonably provide enablement for other biocompatible oils. Office Action at p. 2. Applicants respectfully submit that to satisfy the enablement requirement the specification must contain "sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention" M.P.E.P. § 2164.01. Furthermore, "[t]he test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation" (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP §2164). Contrary to the assertions in the Office Action, Applicants submit that the specification provides sufficient guidance to enable one of skill in the art to select a suitable biocompatible oil. For example, toxicology of an oil intended for *in-vivo* use may be determined after one or more toxicity analyses that are known to those skilled in the art. (see e.g.

p. 8 ll. 4-6 of the instant specification). Such toxicology tests can include, for example, the study outlined in Example 4, p. 43 of the specification. Non-limiting examples of biocompatible oils include those oils as described in the specification at, for example, p.30, ll. 15-17 which states: “[e]xamples of potentially biodegradable oils include oils derived from plants and animals, vegetable oils, paraffin oils, or triglyceride derivatives such as MIGLYOL® or mixtures thereof.” A person of ordinary skill is thus reasonably apprised of which oils, including those oils recited in the instant specification, claims 1, 5-31, and 34-41 encompass and accordingly, the specification enables the skilled artisan to make and use the claimed invention without undue experimentation. As the Examiner indicates, some oils are not toxic by one way of administration, and toxic by another. It is respectfully submitted that one of skill in the art can ascertain which oils are biocompatible without undue experimentation, using for example, as the Examiner points out, a desk reference such as Remington’s. Accordingly, withdrawal of these rejections under §112, first paragraph, is respectfully requested.

Claims 13-18, 21, 23 and 28-29 stand rejected under 35 U.S.C. § 112, second paragraph. The Examiner asserts that there is insufficient antecedent basis for the phrase “said biocompatible oil, and all other biocompatible oils.” Applicants respectfully disagree. However, solely to expedite prosecution, the phrase “all other biocompatible oils” has been removed from claims 13-18 and 23. Claims 21 and 28-29 are canceled. Accordingly, withdrawal of these rejections under §112, second paragraph, is respectfully requested.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1 and 27-38 stand rejected under 35 U.S.C §102(b) as being anticipated by Samejima et al. (JP 1001441). The Examiner asserts that “Samejima et al. teaches a local anesthetic composition [that] may contain lidocaine and sesame oil.” Applicants respectfully assert that the English translation of Samejima does not disclose a flowable pharmaceutical composition comprising a biocompatible oil and a therapeutically effective amount of a pharmaceutically acceptable salt of a caine analgesic agent, wherein said salt of said analgesic agent comprises at least about 3% and no more than about 80% by weight of said flowable pharmaceutical composition, wherein said flowable pharmaceutical composition is suitable for administration to a patient by injection, as recited in amended claim 1, and by reference

dependent claims 30-38. Claims 27-29 have been canceled, rendering the rejection of these claims moot. Samejima et al. discloses only topical compositions that include large proportions of hard fat, for example, on pp. 8-9 of the Samejima translation. Samejima does not disclose a flowable composition that includes, at least about 3% by weight, of a salt of a caine analgesic, and therefore Applicants respectfully request reconsideration and withdrawal of this rejection of claims 1 and 27-38.

Claims 1-19 and 34-41 stand rejected under 35 U.S.C § 102(b) as being anticipated by U.S. Patent 2,625, 501 (the “’501 patent”). The Examiner asserts that the ’501 patent “teaches a parenteral composition comprising sesame oil and cotton seed oils in about 98% of the composition and about 2% morphine sulfate salt”). Applicants respectfully note that the ’501 patent, rather than teaching a composition containing morphine salt and an *oil*, discloses a composition containing morphine salt and a **soap**: “[t]he mixed oils *are then reacted* with a base, such as alcoholic sodium hydroxide, for the purpose of standardizing the mixture at a pH value of 6.5, or slightly below, *and at the same time form a soap of the fatty acids.*” ’501 patent, col. 1, ll. 49-50 - col. 2, ll. 1-4. (emphasis added). As discussed with the Examiner during the interview, soaps are formed from esters in the oil reacting with sodium hydroxide, and this reaction forms **sodium salts of alkanoic acids**, not oils. The ’501 patent discloses that morphine salts are added to these soaps, and not to the oils. ’501 patent, col. 2, ll. 6-7. Therefore, the ’501 patent does not teach a composition comprising a biocompatible oil and at least about 2% by weight of a pharmaceutically acceptable salt of an analgesic agent, as recited in claim 39, and dependent claim thereon.

Further, the ’501 patent discloses only morphine sulfate, not salts of caine analgesics as recited in amended claim 1, claims 2-18 and 34-38 dependent thereon, and claim 41. Applicants assert that one of skill in the art recognizes that morphine sulfate has significant structural and chemical differences and properties as compared to salts of caine analgesics. Applicants therefore respectfully request reconsideration and withdrawal of these rejections based on the disclosure of the ’501 patent.

Claims 1-12, 27, and 30-38 stand rejected under 35 U.S.C § 102(b) as being anticipated by U.S. Patent 3,105,793 (the “’793 patent”). Limitations of original claim 20, which has not

been rejected under this reference, has been incorporated into amended claim 1. Accordingly, the '793 patent does not disclose a composition wherein the salt of a caine analgesic comprises at least about 3% and no more than 80% by weight of a flowable composition, as recited in claim 1 and dependent claims thereon. Applicants therefore respectfully request reconsideration and withdrawal of these rejections based on the disclosure of the '793 patent.

Claim Rejections under 35 U.S.C §103(a)

Claims 20-26 stand rejected under 35 U.S.C § 103(a) as being unpatentable over the '501 patent. Applicants respectfully submit that this reference, for the reasons discussed above, does not disclose all the limitations of the amended independent claims on which these rejected claims depend. Nor does it suggest modifications of the teachings therein which would produce all limitations of the claimed invention. Further, claims 20 and 21 have been canceled, rendering rejection of these claims moot. Accordingly, the Applicants respectfully request withdrawal of this rejection.

Claims 28-29 stand rejected under 35 U.S.C § 103(a) as being unpatentable over the '793 patent. Claims 28-29 have been canceled, rendering this rejection moot. Accordingly, the Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to **Deposit Account No. 06-1448, GPT-029.01.**

Respectfully submitted,
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